





September 24, 2018

TSCA Confidential Business Information Center (7407M)  
WJC East – Room 6428 Attn: TSCA CBI Substantiations  
U.S. Environmental Protection Agency  
1201 Constitution Avenue, NW  
Washington, DC 20004-3302

Subject: Substantiation of Confidential Business Information for 


 Corporation] asserts and substantiates this CBI information with the understanding that the Agency will maintain this information as confidential. If the Agency denies in part or in total this CBI claim, then it is our understanding that the EPA will notify  with respect to the reasons for denial in accordance with §14(g)(1)(B).

 Corporation is responding to the courtesy call placed by Rosalva Tapia on August 8, 2018 and is providing substantiation information for confidentiality claims of site identity (PMN Page 8) and Worker Exposure (PMN Page 9).

Identified below are the appropriate information element(s) that we are substantiating. For any information element that is not specifically identified as subject to a confidentiality claim and substantiated as such in our response, it shall be determined that we have waived our CBI claim, pursuant to 40 C.F.R § 2.205(d).

- Operation Description – Identity PMN Page 8
    - Name, Site address, City, County, State, Zip code
  - Worker Exposure – Worker Activity Column (1), PMN Page 9
1. For what period of time do you request that the information be maintained as confidential, e.g., until a certain date, until the occurrence of a specified event, or permanently? If the occurrence of a specific event will eliminate the need for confidentiality, please specify the event.

Response:

-  Corporation requests that the information should be maintained as confidential indefinitely. This applies to all items listed above, and all attachments.
2. To the extent your business has disclosed any information to others (both internally and externally), what precautions has your business taken? Please identify the measures or internal controls your business has taken to protect the information claimed as confidential.



Response:

- [REDACTED] Corporation has taken any number of measures to protect the confidentiality of its business information. The measures can be divided into four major areas: personnel access, site security, document security, and computer security.

- Personnel Access:

Access to confidential business information is restricted to individuals who specially require such information in order to adequately perform their job function and responsibilities.

Persons other than [REDACTED] Corporation employees are not given access to electronic systems storing confidential business information. Customers, competitors, and the public may be aware that a product is being manufactured or imported through promotional material, technical data sheets and Material Data Sheets. However, these documents would provide generic descriptions only, thus maintaining confidentiality, in many cases, of detailed formulations.

Such confidential business information is not made available to the public nor to customers unless they have signed a non-disclosure agreement.

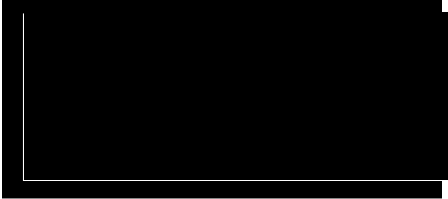
- Document Security:

All [REDACTED] confidential business information it is marked "CONFIDENTIAL". The information is kept in locked filing cabinets. These filing cabinets are kept locked after office hours or whenever the responsible party is away from the area. Only the parties directly responsible for the confidential information are permitted to have keys. All confidential information is kept on site. Any confidential information which is to be discarded is first destroyed by on-site shredding or is discarded into a locked storage bin who contents is then shredded by a third part supplier.

[REDACTED] maintains information as confidential by employing such measures as (1) numbering and tracking all laboratory notebooks; (2) controlling information discussed with persons outside [REDACTED] by having a Supplier Contact Manager who controls and is present at all technical meeting with our suppliers; (3) controlling information discussed with persons outside [REDACTED] by management review of all information released to customer; (4) protecting information released in situations where there is technical collaboration between [REDACTED] and outside companies by means of secrecy agreements with long-term protection following termination of the relationship; and (5) informing employees of their obligation to hold such information a confidential if they should leave [REDACTED]

- Computer Security:

Access to all computer information is protected by password security at the system, sub-system, and file levels, with different passwords for each. Passwords are assigned to individual on a limited need-to-know basis, are changed as required and are administered by the Manager, Information Technology as Security Administrator.



Access to computer hardware is restricted by use of key lock and secret code systems. In addition to these measures, [REDACTED] is using a mandatory “smart card” to log in the individual computers. [REDACTED] uses a robust firewall system to protect its network and information.

- Site Security:

[REDACTED]

When not occupied, the building is protected by an alarm system covering all entrances and spaces by the detection of sound. When the building is occupied, access at both front and rear entrances is monitored by the security personnel. Both front and rear entrances are equipped with a key card system, which is electronically triggered to open only when proper identification is scanned. All visitor are requested to sign in. Visitors are accompanied by [REDACTED] employees while on the premises.

These practices generally apply to all [REDACTED] sites, and to all items listed above, and all attachments.

3. Does any of the information claimed as confidential appear in any public documents, including (but not limited to) safety data sheet, advertising, or promotional material, professional or trade publication, or any other media or publications available to the general public?

Response:

- To the best of our knowledge and after inquiry of those in the business who identify the need for confidentiality in this case, neither the identity of this substance nor [REDACTED] intent to manufacture the product and sell it commercially have been disclosed publicly. This applies to all items listed above.

4. Is there any means by which a member of the public could obtain access to the information? Is the information of a kind that you would customarily not release to the public?

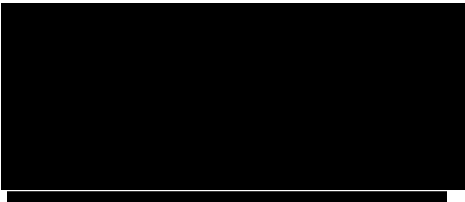
Response:

- This confidential information is not available to third parties, whether our competitors, our customers, our suppliers, or any other party, without our consent. No such information is shared outside of this company except within the scope of a secrecy agreement and for compelling business reasons. Disclosure to customers is only done via a signed confidentiality agreement. This applies to all items listed above, and all attachments.







5. Has any governmental body made a determination as to the confidentiality of the information? If so, please attach a copy of the determination.

Response

[REDACTED]

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- To the best of our knowledge, no other governmental body made a determination as to the confidentiality of the information. This applies to all items listed above.
6. Will disclosure of any information element claimed as CBI likely result in substantial harm to your business's competitive position?

Response:

- Disclosing the information stated above would be harmful to our competitive position. It may provide a useful insight into the direction of our research activities. If this information is known to the competitors, they may replicate our product without investing into research and development and offer it at a lower price.
  - Company Identity and all associated information (i.e., address, location, technical contact information, phone number,  unique identifier):
    - All information related to this product technology, including company and personnel information, must remain confidential, as it would reveal to competitors that we are commercializing in this area. If our company information is made public, it would also allow our competitors to track the amount of research in this area, thus allowing them key insight to our financial investments and anticipate our analysis of market developments that would cause a loss of our competitive advantage should competitors become privy to the information.
    - It is  assertion that the chemical identity in combination with the company and personnel information represent would reveal a current and potential future commercial investment target of  which may help reveal the general direction of  strategy.  further substantiates that CBI claim by recognizing this information as being subject to exemption under 5 U.S.C. §552(b)(4).
  - Worker Activity and all associated information (Column 1 Worker activity description):
    - If this information is made public, it would allow our competitors to gain knowledge of our manufacturing process and gain key insight into the identity of the PMN substance. Our competitors could use this knowledge to take business from us. For example, our competitors could offer the PMN substance at a lower price because they would not have to recoup the development cost incurred, nor would they need to expend the capital and effort in the extensive approval process or in obtaining industry acceptance. Instead, we would be making all the investments, while they could avoid all of the overhead and instead merely come in with a "me-too" product at a substantially lower price.
7. Do you assert that the information is submitted on a voluntary or a mandatory basis? Please explain the reason for your assertion. If you assert that the information is voluntarily submitted information, please explain whether the information is the kind that would customarily not be released to the public.
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Response:

- Submission of any available data with PMNs is mandatory by the agency. This applies to all items listed above, none of which [REDACTED] is submitting voluntarily.
8. Whether you assert the information as voluntary or involuntary, please address why disclosure of the information would tend to lessen the availability to the EPA of similar information in the future.

Response:

- While submission of this information is mandatory by the EPA, this would not change our position to file an PMN. This applies to all items listed above, and all attachments.

We would also note that the disclosure of this information, provided in support of a TSCA Section 5 notification, would not affect EPA's availability of information to disclose under TSCA Section 26(j), which is concerned more with TSCA Sections 4 and 6.

If EPA disclosed this kind of information in the face of [REDACTED] claims, [REDACTED] and the rest of the US chemical industry would become less inclined to want to share this kind of information with EPA in the future, as participants in the US chemical industry would not have any assurance of protecting the confidentiality of the significant investments in their new substance/formulation/technologies, and therefore would be unable to protect their investment through the use of trade secret protections. The efforts of some parties to establish or grow market share through the aggressive use of competitive intelligence already makes it difficult to identify, deter or delay the introduction of third party copy-cat products, often at reduced sales price, given the significantly lower investment such copy-cats have incurred to come to market. The disclosure of this sensitive information would also support the rise and commercial success of lower quality counterfeit products, sold under the guise of the trademarked product. Were EPA to insist on the disclosure of sensitive information, the US chemical industry members would probably see and encourage Congressional action to limit EPA's ability to require such information in support of a TSCA Section 5 notification.

9. Does any of the information you are claiming as CBI contain (a) trade secret(s)?

Response:

- [REDACTED] holds marketing information as trade secret, the release of site and worker exposure information would enable a competitor to gain knowledge of our manufacturing processes and marketing and sales.
- [REDACTED] holds marketing information as trade secret, as the release of site and worker exposure information would result in potential economic benefit to competitors; as this information is not readily ascertainable through publicly available means. This





would allow our competitors to gain the knowledge of markets without devoting resources and time to identify potential opportunities.

10. Explain any other issue you deem relevant (including, if pertinent, reasons why you believe that the information you claim to be CBI is not emission data or effluent data).

Response:

- Not applicable to this PMN.

If you have any other questions, I can be reached at 

Sincerely,

